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### 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Date: July 16, 1996  
Trade Name: 3M™ Dent System  
Common Names: resin tooth bonding agent system,  
resin-based dental adhesive system  
Classification Name: resin tooth bonding agent (21CFR872.3200)  
Predicate devices:  
3M™ Scotchbond™ Multi-Purpose Plus Dental Adhesive System (K942493)  
Prime & Bond™ Direct Composite Bonding Agent (K951864)  
One Step™ Universal Dental Adhesive System (K# unknown)

The 3M™ Dent System is a simple adhesive system that offers the dental practitioner a wide range of applications. The 3M™ Dent System is substantially equivalent to the predicate devices above in that all are intended to be used as a 21 CFR 872.3200 resin tooth bonding agent. 3M™ Dent System is substantially equivalent to One Step™ Universal in terms of indications.

The design of the 3M™ Dent System is substantially equivalent to the predicate devices above because all utilize a phosphoric acid etchant and a methacrylate resin that will polymerize upon exposure to visible light from a dental light curing unit. The 3M™ Dent System, Prime & Bond™ and One Step™ Universal all utilize a resin that is intended to function as both primer and adhesive.

The performance of the 3M™ Dent System is substantially equivalent to the predicate devices above, based on nonclinical performance data including bond strength to dentin, enamel and various dental materials, dentin permeability and microleakage.

Biological safety assessment, conducted in accordance with ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (with FDA modified matrix), does not raise any new safety concerns and indicates that 3M™ Dent Resin is safe for its intended use. The phosphoric acid etchant component of the 3M™ Dent System has already been legally marketed globally for several years with another 3M dental adhesive system. Use of this phosphoric acid etchant as part of the 3M™ Dent System does not raise any new safety concerns. Refer to precautionary language in the 3M™ Dent Instructions for Use.